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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,341	06/03/2005	Cherk Shing Tam	32404-2147	3458

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EXAMINER	
KOSSON, ROSANNE	
ART UNIT	**PAPER NUMBER**
1652	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,341	TAM, CHERK SHING	
	Examiner	Art Unit	
	Rosanne Kosson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, drawn to an isolated polypeptide comprising one defined sequence that corresponds to Formula I, a pharmaceutical composition comprising this polypeptide, and a method of making the pharmaceutical composition.

Group II, claim(s) 6, 11 and 19-22 (the second claim 20), drawn to an isolated polypeptide having the sequence of SEQ ID NO: 1, a pharmaceutical composition comprising this polypeptide, and a method of making the pharmaceutical composition.

Group III, claim(s) 6, 12 and 19-22 (the second claim 20), drawn to an isolated polypeptide having the sequence of SEQ ID NO: 2, a pharmaceutical composition comprising this polypeptide, and a method of making the pharmaceutical composition.

Group IV, claim(s) 6, 13 and 19-22 (the second claim 20), drawn to an isolated polypeptide having the sequence of SEQ ID NO: 3, a pharmaceutical composition comprising this polypeptide, and a method of making the pharmaceutical composition.

Group V, claim(s) 6, 14 and 19-22 (the second claim 20), drawn to an isolated polypeptide having the sequence of SEQ ID NO: 4, a pharmaceutical composition comprising this polypeptide, and a method of making the pharmaceutical composition.

Group VI, claim(s) 6, 15 and 19-22 (the second claim 20), drawn to an isolated polypeptide having the sequence of SEQ ID NO: 5, a pharmaceutical composition comprising this polypeptide, and a method of making the pharmaceutical composition.

Group VII, claim(s) 6, 16 and 19-22 (the second claim 20), drawn to an isolated polypeptide having the sequence of SEQ ID NO: 6, a pharmaceutical composition comprising this polypeptide, and a method of making the pharmaceutical composition.

Group VIII, claim(s) 17-18, drawn to a method of stimulating bone growth or treating osteoporosis, comprising administering to a mammal a therapeutically effective amount of an isolated polypeptide comprising one defined sequence that corresponds to Formula I.

Group IX, claim(s) 17-18, drawn to a method of stimulating bone growth or treating osteoporosis, comprising administering to a mammal a therapeutically effective amount of an isolated polypeptide having the sequence of SEQ ID NO: 1.

Group X, claim(s) 17-18, drawn to a method of stimulating bone growth or treating osteoporosis, comprising administering to a mammal a therapeutically effective amount of an isolated polypeptide having the sequence of SEQ ID NO: 2.

Group XI, claim(s) 17-18, drawn to a method of stimulating bone growth or treating osteoporosis, comprising administering to a mammal a therapeutically effective amount of an isolated polypeptide having the sequence of SEQ ID NO: 3.

Group XII, claim(s) 17-18, drawn to a method of stimulating bone growth or treating osteoporosis, comprising administering to a mammal a therapeutically effective amount of an isolated polypeptide having the sequence of SEQ ID NO: 4.

Group XIII, claim(s) 17-18, drawn to a method of stimulating bone growth or treating osteoporosis, comprising administering to a mammal a therapeutically effective amount of an isolated polypeptide having the sequence of SEQ ID NO: 5.

Group XIV, claim(s) 17-18, drawn to a method of stimulating bone growth or treating osteoporosis, comprising administering to a mammal a therapeutically effective amount of an isolated polypeptide having the sequence of SEQ ID NO: 6.

The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reason: the specification makes it abundantly clear that each polypeptide is different from the other polypeptides. Therefore, no technical feature is present in all of the groups presented. Because no technical feature links all of the groups, no special technical feature is present that represents an advance over the prior art. Therefore, each invention lacks unity with any of the others.

Further, an international application containing claims to different categories of inventions will be considered to have unity of invention if the claims are drawn only to one of certain combinations of categories:
(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
(4) A process and an apparatus or means specifically designed for carrying out the said process; or
(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process (see 37 CFR 1.475(b)-(d)). In the instant case, the claims are drawn to multiple products and a processes,

only a particular combination of which along with Group I may be considered for unity of invention, i.e., Group I and Group VIII, (the first named product and the first named process of using the product). Other groups are drawn to additional products and processes, and other combinations do not comply with the aforementioned Rules. But, because a corresponding special technical feature is not present, Groups I and VIII cannot be considered to have unity of invention.

Accordingly, a holding of lack of unity of invention is proper.

Should Group I be elected, further restriction is necessary. Claim 1 cannot be searched, because each variable (each X) is indefinite, and claim 2 recites 20,000 different sequences. Applicants are required to elect one single amino acid sequence corresponding to Formula I for prosecution on the merits. Applicants are required to indicate one definite amino acid that corresponds to each of amino acids 1-8 and 10.

The searches for any one group (or sequence) are not required for and are not coextensive with the searches for any other group (or sequence), thereby creating an undue burden of search and examination. The results from a search of each of these groups have different considerations with respect to the prior art. Burden lies not only in the search of U.S. patents, but also in the search for literature and foreign patents and in examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness, written description and enablement.

Applicants must choose **ONE** polypeptide from among those claimed as indicated in the different groups above. Each polypeptide sequence is a distinct invention requiring separate searches. THESE ARE NOT SPECIES. Each sequence is a chemically, structurally and functionally distinct molecule. Therefore, the each of these polypeptides and each of these polynucleotides is patentably distinct.

Moreover, each sequence requires a separate set of searches. Applicants should note that searching each sequence imposes a serious search burden. Currently, there are approximately eight different databases that accompany the results of a search for <u>one</u> discrete

amino acid or nucleic acid sequence, and each result set from a particular database must be carefully considered. Each set of prior art has its own considerations with respect to anticipation and obviousness. Hence, the search for even two different polypeptides or polynucleotides in the databases, in addition to searching the organic molecule databases, would require extensive searching and review. Therefore, these inventions are patentably distinct.

Applicant is advised that a reply to this requirement must include an identification of the polypeptide that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

This election requirement is not be construed as a species election, as these compounds do not share a common primary structure and appear to be patentably distinct.

Should applicant traverse on the ground that these different compounds are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652

rk/2006-12-18

Rosanne Kosson

ROBERT A. WAX
PRIMARY EXAMINER